Actions Taken by FDA Center for Veterinary Medicine

The following corrections or additions to the January 2005 list were published in the Federal Register in December 2004.

New Approvals

NADA Number: 141-240

Trade Name:	ReBalance™ Antiprotozoal Oral Suspension		
Ingredients:	Sulfadiazine, pyrimethamine		
Sponsor:	Animal Health Pharmaceuticals, LLC		
Approval Date:	November 5, 2004		
Status:	Prescription only		
Route:	Oral		
Species:	Horses		
Drug Form:	Liquid (suspension)		
Concentration:	250 milligrams sulfadiazine and 12.5 milligrams pyrimethamine per milliliter		
Indications:	For the treatment of horses with equine protozoal myeloencephalitis (EPM) caused by *Sarcocystis neurona*.		
Patent Number:	5,747,476	Expiration date:	July 17, 2016
	6,255,308		July 17, 2016
	6,448,252		July 17, 2016
Exclusivity:	3 years		

21CFR 520.2215 & 510.600

ANADA Number: 200-382

Pioneer Product:	102-380
Trade Name:	Furosemide Syrup 1%
Ingredients:	Furosemide
Sponsor:	Phoenix Scientific, Inc.
Approval Date:	November 18, 2004
Status:	Prescription only
Route:	Oral
Species:	Dogs
Drug Form:	Liquid (syrup)
Concentration:	10 milligrams per milliliter
Indications:	For use alone or in combination with furosemide injection in the treatment of edemama, pulmonary congestion, or ascites associated with cardiac insufficiency and acute non-inflammatory tissue edema.

21CFR 520.1010

Supplemental Approvals

This section displays only the change(s) to the original approval. To read the complete approval please refer to 21CFR Parts 500 and related Federal Register notices.

NADA Number: 009-576

Approval Date: October 28, 2004

This application provides for revised labeling that this product is not for use in veal calves which modifies the existing approval for cattle, and that a withdrawal period has not been established in preruminating calves.

21CFR 522.1940

Actions Taken by FDA Center for Veterinary Medicine

NADA Number: 110-315

Approval Date: October 28, 2004

This application provides for revised labeling that this product is not for use in veal calves which modifies the existing approval for cattle, and that a withdrawal period has not been established in preruminating calves.

21CFR 522.1940

NADA Number: 138-612

Approval Date: October 28, 2004

This application provides for revised labeling that this product is not for use in veal calves which modifies the existing approval for heifers, and that a withdrawal period has not been established in preruminating calves.

21CFR 522.2476

NADA Number: 141-064

Approval Date:	November 24, 2004
Species:	Swine, female breeding
Indication	For the control of swine respiratory disease associated with *Actinobacillus pleuropneumoniae* and *Pasteurella multocida* when used in female breeding swine.
Exclusivity:	3 years

This application provides for use in female breeding swine which modifies the existing approval for swine for the indication listed.

21CFR 558.618

ANADA Number: 200-224

Approval Date: October 22, 2004

This application provides for revised labeling that this product is not for use in veal calves which modifies the existing approval for beef heifers and steers, and that a withdrawal period has not been established in preruminating calves.

21CFR 522.2476

Addition of Sponsor

Animal Health Pharmaceuticals, LLC
1805 Oak Ridge Circle, suite 101
St. Joseph, MO 64506
Drug Labeler code: 068718

Change of Sponsor Address

Alstoe, Ltd. Animal Health
Pera Innovation Park
Nottingham Road
Melton Mowbray
Leicestershire, England LE13 OPB
Drug labeler code: 062408

Pharmacia & Upjohn Co.
a Division of Pfizer, Inc.
235 East 42d St.
New York, NY 10017
Drug labeler code: 000009

Addition of Patent Number

NADA Number: 141-200

Patent Number:	Expiration Date:
4,678,463	March 1, 2005
6,423,039	June 22, 2017
6,663,608	June 22, 2017

Suitability Petition Action

Number:	04P-0551/CP1
Sponsor:	Intervet, Inc.
Petition:	Request permission to file an ANADA for a generic new animal drug ivermectin which differs from the pioneer product, UlcerGard™, Merial Ltd., NADA 141-227 by the following characteristics: The generic product will have a different dosage form (tablet) from the pioneer.
Action:	Filed December 21, 2004.

Technical Amendment

The Food and Drug Administration (FDA) is amending the animal drug regulations to remove conditions of use in cattle and chickens for a coumaphos Type A medicated article for which approval was withdrawn at the sponsors request, on July 3, 1996 (61 FR 34727). At this time, FDA is amending the regulations in Section 558.185 to reflect the remaining approved uses of coumaphos in medicated cattle feeds. This rule is effective December 2, 2004.

The Food and Drug Administration (FDA) is amending the animal drug regulations to add the approved withdrawal time to the limitations to conditions of use for chlortetracycline Type C medicated feeds for chickens when fed at the 500 gram per ton level. The approved 24-hour withdrawal time at this dose level was inadvertently removed for all sponsors at the time of a supplemental approval of a zero-day withdrawal time for AUREOMYCIN Type C medicated chicken feeds under NADA 048-761 (63 FR 57245 at 57247, October 27, 1998). At this time, FDA is amending the regulations to correct this error in 21 CFR 558.128. This action is being taken to improve the accuracy of the regulations. This rule is effective December 30, 2004.